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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,429	03/15/2004	Atsuo Ito	04853.0081-01000	3532

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,429	ITO ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/984,947.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka et al. (2000) or Otsuka et al. (October 1999), each in further view of EP 0 702 954, White (US Pat. 3,897,575) and Knights et al. (US Pat. 5,766,330).

Otsuka et al. (2000) or Otsuka et al. (October 1999) teach the treatment of zinc-deficient osteoporosis with zinc tricalcium phosphate and discloses a 0.6% ZnTCP in simulated body fluid containing sodium, potassium, magnesium, chloride ion, calcium, bicarbonate ion, sulfate ion and hydrogen phosphate ion (See documents in their entirety).

EP 0 702 954 teaches that Vitamin D and minerals such as calcium, zinc and phosphate protect against disorders of bone loss (Pg. 2, lines 33-53). It is taught that the compositions can contain emulsifiers such as mono and diglycerides of long chain fatty acids and propylene glycol esters as well as pharmaceutically acceptable carriers and excipients which are known to those skilled in the art (Pg. 3, lines 10-13). It is taught that the liquid dosage form may contain suitable solvents, emulsifying agents, suspending agents and diluents which are known to those skilled in the art (pg. 3, lines 18-20).

White discloses the preparation of zinc containing alpha-tricalcium phosphate which is used as a nutritional supplement (Column 5, lines 32-60).

Knights et al. disclose a method of preparing a suspension of calcium salts, such as tricalcium phosphate which do not separate or sediment and contains safflower oil (Abstract, Column 8, Table III, Claim 4).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of zinc containing calcium phosphate and sedimentation velocity of less than 0.8 cm/s, Vitamin D and the water-immiscible solvents. However, the prior art amply suggests the same as the preparation of suspensions which do not separate or sediment are disclosed in the art and vitamin D, zinc, calcium, and phosphate are disclosed in the art to used together for treatment of bone loss and suitable solvents for liquid preparations are known to those skilled in the art. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would treat zinc deficient osteoporosis and allow preparation of nutritional drinks which do not have sediment.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that there is no teaching in Otsuka as to sedimentation velocity, however, Knights et al. discloses the preparation of suspensions which do not sediment. As such, the prior art suggests product which will have a sedimentation velocity of approximately zero.

Applicant argues that the Otsuka references do not teach the use of a calcium phosphate glass. However, Applicant has provided no evidence that heating the precipitate to 850 degrees Celsius results in a significantly different product than zinc TCP prepared at 980 degrees Celsius or that heating at a temperature of 850 degrees Celsius does not produce a zinc containing

calcium phosphate glass. For example, see US Pat. 4,243,567 which discloses temperatures as low as 800 degrees Celsius for the preparation of a phosphate glass (Column 3, lines 24-34). The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 45 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Further, it is noted that the features upon which applicant relies (i.e., preparation temperature of 980 degrees Celsius or higher) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to claims 19, 20, Examiner reiterates the response above. Further, one of ordinary skill in the art would expect based on the teachings of the prior art that alpha and beta ZnTCP could be used interchangeably as nutrient supplements. See In re Dillon, 16 USPQ2d 1897,1901 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). As such, notwithstanding the fact that Otsuka (1999) may also be referring to beta-ZnTCP (Applicant's evidence is at best circumstantial), this does not overcome the rejection herein over claims 19 and 20. Applicant's reference to reaction temperatures does not overcome the rejection as the use of zinc containing alpha TCP is disclosed in the art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
December 22, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600